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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,921	09/24/2001	Didier Raoult		3015

7590 07/28/2004

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,921	RAOULT ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *6-9, 12-24 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10,11 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/5/01& 5/13/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 4/28/04 is acknowledged.

Specification Informalities withdrawn

2. In view of various amendments made to the Specification in response to First Action On Merits, the specification informalities are withdrawn.

Election/Restriction

3. Applicant continues to traverse the restriction made under 35 U.S.C. 121 and 372. The examiner has answered all the issues raised by the applicant in the previous office action. However, the examiner again chose to reply to applicant's arguments.

Applicant asserts that including claims 16, 17 and 26 is neither an oversight nor a typographical error.

As examiner stated clearly in the previous office action that the examiner regrets the oversight made in the restriction requirement in placing claims 16-17 and 26 in Group I and III. However, claims 16 and 17 drawn to a kit are placed rightly along with claim 13, drawn to a method for serological diagnosis of whipple's disease in group V. Similarly claim 26 drawn to a kit is placed along with the method claims 14—15 in-group VI. However, claim 25 is placed along with the claims 1-5 and 10, 11 in-group I as requested by the applicant.

With respect to Groups I, II, IV, V and VI, the applicant is misinterpreting the examiner's statement. Examiner stated that although the applicant's concept "bacterium" **may** link Group I, III, IV, V and VI such concept **does not constitute a special technical feature** as defined by PCT Rule 13.2 (37CFR1.475(a) because the expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Specifically Schoedon et al 1997 teach i.e.,

isolation of *Tropheryma whippelii* bacterium (see Journal Infectious diseases, 176; 672-677) responsible for Whipple's disease. Therefore, it does not constitute a special technical feature by definition. Therefore, lack of unity exists.

Similarly applicant is misinterpreting the examiner's statement on Group III, drawn to an antibody. The examiner stated that the special technical feature of Group III is considered to be an antibody that share no common structure, function and property with Group I claims. It was never stated that the special technical feature is "bacterium" rather the examiner stated that there is no inventive concept in claim 1 and hence unity of invention is lacking in-group I. Since there is no special technical feature exists in claim 1, groups IV, V and VI drawn to different methods are restricted and placed in different groups accordingly. Similarly Groups II and VII drawn to nucleic acid and methods using nucleic acids are restricted and placed rightly in different groups. The special technical feature is not bacterium as applicant stated in the response.

Additionally, restriction made by the examiner is not based on dependency of claims but based on lack of unity among groups under 35 U.S.C. 121 and 372. Further, amino acids, nucleic acids and antibodies (Inventions I, II and III respectively) do not share a common structure, common property or common function. Therefore, there is no special technical feature exists among these products as well as methods of using said products.

Status of claims

4. Claims 1-28 are pending

Claims 1-28 have been amended

Claims 1-5, 10-11and 25 are under examination.

Claims 6-9, 12-24, 26-28, are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Information Disclosure Statement

5. Information Disclosure Statement filed on 12/5/01and 5/13/02 were considered and a signed copy of each was attached to the office action mailed on 1/28/04. As per applicant's request, the same is attached to this Office action.

Claim Rejection - 35 USC 112, second paragraph withdrawn

6. In view of amendment to the claims, the rejection under 35 USC § 112, second-paragraph is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

7. The rejection of claims 1-5, 10 –11 and 25 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the bacterium or hybridoma cell lines of the invention, a suitable deposit for patent purposes, evidence of public availability of the cell lines of the invention or evidence of the reproducibility without undue experimentation of the monoclonal antibodies is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Applicants' arguments filed on 4/28/04 have been fully considered and are not deemed to be persuasive for the following reasons:

Applicant states that the specification is amended to recite the deposit information and a copy of the receipts for the deposits of the bacterium and hybridoma is attached to the response filed by the applicant 4/28/04. Further applicant states that as Applicants made the deposits under the provisions of the Budapest Treaty and amended the specification to recite the address of the depository and deposit dates. Thus, Applicants have satisfied the requirements of 35 U.S.C. j112, first paragraph and therefore the rejection should be withdrawn.

The examiner has reviewed the amendment to the specification indicating the deposit information. Although the specification contains bacterium and hybridoma clone deposit numbers and dates of deposit, it is not clear that the bacterium and hybridoma cell line are known and publicly available. Further, the examiner has indicated in the previous Office action as set forth above that If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing

the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

The examiner acknowledges the receipts for the deposits of the bacterium and hybridoma filed on 4/28/04. All the deposit information filed on 4/28/04 is in a foreign (French) language. Since the Examiner is not versed in this language, these documents have been placed in the application. However, Applicant is advised to submit the certified translations of said documents. In view of lack of affidavit or declaration by applicant or assignees and lack of submission of copy of the contract with the depository for deposit and maintenance of each deposit, this rejection is maintained.

Claim Rejection - 35 USC 102 maintained

8. The rejection of claims 1-2 and 4 under 35 U.S.C. 102(b) as being anticipated by Schoedon et al 1997 is maintained as set forth in the previous Office action.

Schoedon et al disclose isolation of *Tropheryma whippelii* bacterium (see Journal Infectious diseases, 176; 672-677) responsible for Whipple's disease (see abstract) from biopsy material obtained from a patient. The bacterium is cultured in medium containing (see figure1) deactivated mononuclear phagocytes (see page 673, right column, under inoculation of cultures) and thus read on claim 1.

Claim 2 " Bacterium obtained from a culture of human fibroblasts after at least 2 months of incubation in a culture medium based on MEM" is a product-by-process claim. Although product-by-process claims are limited and defined by the process, nonetheless, determination of patentability is based on the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or an obvious variant of the product of the prior art, the claim is unpatentable even though the product was made by a different process. The recitation of a process limitation in claim 2 is not seen as further limiting the claimed product, as it is presumed the equivalent products can be obtained by multiple routes. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best* 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Figure 5 would read on antigen of bacterium as periodic acid-Schiff inclusion in bacterium has been identified. The prior art anticipated the claimed invention.

Applicants' arguments filed on 4/28/04 have been fully considered and are not deemed to be persuasive for the following reasons:

Applicants asserts that the reference cited by the examiner under 35 U.S.C. 102 (b) Schoedon et al appears to describe isolating and culturing *Tropheryma whippelii.* However, after Schoedon was published, it was publicly acknowledged that Tropheryma whippelii cannot be isolated and cultured under the conditions established by Schoedon and that Schoedon's work was not successful. Since Schoedon's work cannot be reproduced, the reference is not enabled, and thus cannot anticipate the subject matter claimed. According to the MPEP: 2121, prior art relied on to anticipate a claimed invention must be enabling. A reference contains an enabling disclosure if the public was in possession of the claimed invention before the date of the claimed invention. In this case, Schoedon fail to put the public in possession of isolated and cultured *Tropheryma whippelii* as evidenced by Raoult et al, The New England Journal of Medicine 342.620-25 (2000) (Didier Raoult, the first named inventor on the subject patent application, is the corresponding author), and Hinrikson et al, International Journal of systematic Bacteriology 49: 1701-06 (October 1999). In addition, applicant cites Relman 's (1997) commentary on Schoedon's work.

The examiner disagrees with the applicant because the prior art clearly isolated the bacterium from infected intestinal biopsy material, cultured and passaged in human macrophages and monoblasts (figure 1 and abstract) and positively identified as *Tropheryma whippelii.* Thus the prior art anticipated claims 1, 2 and 4.

The examiner has carefully reviewed the art of record used by the examiner as well as the comments made by Raoult et al, 2000, Hinrikson et al 1999 and Relman et al 1997 and understands that the first isolation of T. *whippelii.* using human macrophages inactivated with

interleukin-4 and culturing the bacteria was reported in 1997 by Schoedon et al. However, if applicant questions the enablement of the teachings of the prior art and Schoedon fail to put the public in possession of isolated and cultured *Tropheryma whippelii*, then an affidavit which questions the enablement of the teachings of the cited prior art should be submitted (MPEP: 2205). In the absence of evidence to the contrary, this rejection is maintained.

Remarks

9. No claims are allowed.

Conclusion

10. This application contains claims 6-9, 12-24 and 26-28, that are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

7/19/04